Patient No. 1998 • **Gender:** Male • **Age:** 68 • **Tumor Location:** Cervical • **Study No.** 414-94-2 • **Stratum** 1 • **Investigator No.** 0166

TREATMENT GROUP	**CDDP/epi gel**

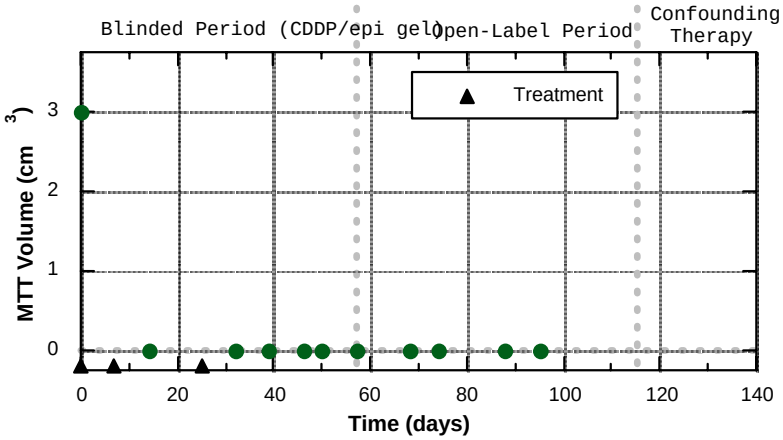
	1° Tx GOAL	*BLINDED PERIOD OUTCOME*
Investigator	Prevent invasion of vital structure	MET
Patient	Pain control	SAME

	TUMOR RESPONSE	*PATIENT BENEFIT*
During the Blinded Period	CR	Yes
Any Time During the Study	CR	Yes

History A 68-year-old white man, was diagnosed with squamous cell carcinoma of the larynx in 4/97. He underwent radiotherapy (5/29/97 to 7/18/97, 200 cGy x 5 per week). A complete response was obtained. He relapsed 1 year later and underwent surgery (10/27/98, right modified neck dissection) followed by chemotherapy with cisplatin/5-FU (11/98 to 1/99, cisplatin 60 mg per day, 5-FU 150 mg per day) in combination with radiotherapy (11/30/98 to 1/6/99, 120 cGy, x 2 per day x 5 days per week). Disease progression was confirmed by biopsy (3/9/99), which demonstrated the presence of moderately differentiated squamous cell carcinoma. On 3/19/99, 2 years after the original diagnosis, the patient was screened for study enrollment. Symptoms included moderate migraine headaches in the past 5 months since neck surgery.

Baseline MTT The MTT (volume 3.0 cm^3) was cervical, located on the right lateral neck. The MTT occurred in a previously radiated field. The investigator's primary treatment goal was prevention of invasion of a vital structure and/or blood vessel. The patient selected a primary treatment goal of pain control.

Blinded Period The patient received 3 CDDP/epi gel treatments to the MTT over 26 days. He had a complete MTT response and benefited from treatment. The tumor response was first observed on Day 15 and had a duration of 103 days (including time in extended follow-up), after which confounding therapy was initiated. The investigator's treatment goal, prevention of invasion of a vital structure and/or blood vessel, was met for 117 days and success was continuing at last observation. Although the patient's primary treatment goal, pain control, was assessed as unchanged, the patient reported 2 unexpected benefits which suggest pain improvement. He could now roll over and lie on the treated side, and he no longer had to "pull his hair to move the head when getting out of a chair". A new cervical tumor that emerged during the blinded period was first treated with CDDP/epi gel on Day 15, and was classified as stable disease. The patient discontinued the blinded period on Day 58.



Extended Follow-Up Phase The patient continued to have a complete MTT response, continued to achieve benefit from treatment, and the investigator's goal continued to be met. The patient received 2 CDDP/epi gel treatments during this study phase for the new cervical tumor that emerged in the blinded period. Its classification remained stable disease. The patient discontinued on Day 126.

Local Cytotoxic Effects The MTT showed no evidence of necrosis,

ulceration, or eschar at baseline. After CDDP/epi gel treatment, eschar peaked at "moderate" from Days 33 to 75 while necrosis peaked at "moderate" between Days 58 and 75. Eschar and necrosis both resolved on Day 96.

Serious Adverse Events The patient experienced no serious, treatment-related adverse events.

Other Significant Adverse Events There was 1 severe, treatment-related adverse event. This event was considered an immediate injection effect: on Day 40, the patient experienced right neck pain immediately following treatment, which lasted 3 days.

Other Disease/Intercurrent Illness The patient had a history of hypertension, chronic obstructive pulmonary disease, gout, arthritis, longstanding tobacco use, and alcohol abuse.